



Sheet 1 of 4

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ATTY DOCKET NO. 47-99	SERIAL NO. 09/350,327	FILING DATE July 9, 1999
APPLICANT Randolph et al.		GROUP 1633

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## U.S. PATENT DOCUMENTS

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
ABG	5,728,804	03/17/98	Sharma et al.	530	350	
ABG	5,714,371	02/03/98	Ramanathan et al.	435	219	
ABG	5,605,691	02/25/97	Carroll	424	184.1	
ABG	5,593,865	01/14/97	Rudolph et al.	435	69.1	
ABG	5,410,026	04/25/95	Chang et al.	530	408	
ABG	5,162,507	11/10/92	Wolfe et al.	530	412	
ABG	5,109,117	04/28/92	Ho	530	399	
ABG	5,077,392	12/31/91	Rudolph et al.	530	402	
ABG	5,064,943	11/12/91	McCoy et al.	530	399	
ABG	5,023,323	06/11/91	Ho	530	399	
ABG	4,985,544	01/15/91	Yokoo et al.	530	399	
ABG	4,923,967	05/08/90	Bobbitt et al.	530	351	
ABG	4,677,196	06/30/87	Rausch et al.	530	412	
ABG	4,659,568	04/21/87	Heilman, Jr.	424	88	
ABG	4,652,630	03/24/87	Bentle et al.	530	344	

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation Yes/No



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## OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

<i>Rg/b</i>		Bam et al. (1998) "Tween Protects Recombinant Human Growth Hormone Against Agitation-Induced Damage via Hydrophobic Interactions" <i>Journal of Pharmaceutical Sciences</i> 87:1554-1559. ✓
<i>Rg/b</i>		Bam et al. (1996) "Molten Globule Intermediate of Recombinant Human Growth Hormone: Stabilization with Surfactants" <i>Biotechnology Progress</i> 12:801-809. ✓
<i>Rg/b</i>		Bowden et al. (1991) "Structure and Morphology of Protein Inclusion Bodies in <i>Escherichia Coli</i> " <i>Bio/Technology</i> 9:725-730. ✓
<i>Rg/b</i>		Carpenter et al. (1997) "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice" <i>Pharmaceutical Research</i> 14:969-975. ✓
<i>Rg/b</i>		Clark et al. (1998) "Oxidative Renaturation of Hen Egg-White Lysozyme. Folding vs Aggregation" <i>Biotechnology Progress</i> 14:47-54. ✓
<i>Rg/b</i>		Da Poian et al. (1994) "Differences in Pressure Stability of the Three Components of Cowpea Mosaic Virus: Implications for Virus Assembly and Disassembly" <i>Biochemistry</i> 33:8339-8346. ✓
<i>Rg/b</i>		Defaye et al. (1995) "Renaturation of Metmyoglobin Subjected to High Isostatic Pressure" <i>Food Chemistry</i> 52:19-22. ✓
<i>Rg/b</i>		DeLoskey et al. (1994) "Isolation and Refolding of H-ras from Inclusion Bodies of <i>Escherichia coli</i> : Refold Procedure and Comparison of Refolded and Soluble H-ras" <i>Archives of Biochemistry and Biophysics</i> 311:72-78. ✓
<i>Rg/b</i>		Fischer, B. (1996) In: <i>Lysozymes: Model Enzymes in Biochemistry and Biology</i> P. Jolles, ed. (Birkhauser-Verlag, Boston) pp. 143-161. ✓
<i>Rg/b</i>		Fischer et al. (1992) "A Novel Sequential Procedure to Enhance the Renaturation of Recombinant Protein from <i>Escherichia coli</i> Inclusion Bodies" <i>Protein Engineering</i> 5:593-596. ✓
<i>Rg/b</i>		Goldberg et al. (1991) "A Kinetic Study of the Competition Between Renaturation and Aggregation During the Refolding of Denatured-Reduced Egg White Lysozyme" <i>Biochemistry</i> 30:2790-2797. ✓
<i>Rg/b</i>		Gorovits and Horowitz (1998) "High Hydrostatic Pressure Can Reverse Aggregation of Protein Folding Intermediates and Facilitate Acquisition of Native Structure" <i>Biochemistry</i> 37:6132-6135. ✓
<i>Rg/b</i>		Heremans and Smeller (1998) "Protein Structure and Dynamics at High Pressure" <i>Biochimica et Biophysica Acta</i> 1386:353-370. ✓
<i>Rg/b</i>		Hevehan and Clark (1997) "Oxidative Renaturation of Lysozyme at High Concentrations" <i>Biotechnology and Bioengineering</i> 54:221-230. ✓



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W.A.B.		Jaenicke and Koberstein (1971) "High Pressure Dissociation of Lactic Dehydrogenase" <i>FEBS Letters</i> 17:351-354. ✓
W.A.B.		Kornblatt et al. (1982) "The Pressure-Induced, Reversible Inactivation of Mouse Brain Enolases" <i>Eur. J. Biochem.</i> 128:577-581. ✓
W.A.B.		Lange et al. (1996) "Pressure Induced Protein Structural Changes as Sensed by 4 <sup>th</sup> Derivative UV Spectroscopy" <i>Progress in Biotechnology</i> 13:135-140. ✓
W.A.B.		Leach and Scheraga (1960) "Effect of Light Scattering on Ultraviolet Difference Spectra" <i>Journal of the American Chemical Society</i> 82:4790-4792. ✓
W.A.B.		Maachupalli-Reddy et al. (1997) "Effect of Inclusion Body Contaminants on the Oxidative Renaturation of Hen Egg White Lysozyme" <i>Biotechnology Progress</i> 13:144-150. ✓
W.A.B.		Maeda et al. (1996) "Effective Renaturation of Denatured and Reduced Immunoglobulin G <i>in vitro</i> without Assistance of Chaperone" <i>Protein Engineering</i> 9:95-100. ✓
W.A.B.		Mitraki and King (1989) "Protein Folding Intermediates and Inclusion Body Formation" <i>Bio/Technology</i> 7:690-697. ✓
W.A.B.		Mitraki et al. (1987) "Quasi-Irreversibility in the Unfolding-Refolding Transition of Phosphoglycerate Kinase Induced by Guanidine Hydrochloride" <i>European Journal of Biochemistry</i> 163:29-34. ✓
W.A.B.		Moore and Leppert (1980) "Role of Aggregated Human Growth Hormone (hGH) in Development of Antibodies to hGH" <i>Journal of Clinical Endocrinology and Metabolism</i> 51:691-697. ✓
W.A.B.		Müller et al. (1982) "Thermodynamics and Mechanism of High-Pressure Deactivation and Dissociation of Porcine Lactic Dehydrogenase" <i>Biophysical Chemistry</i> 16:1-7. ✓
W.A.B.		Oberg et al. (1994) "Nativelike Secondary Structure in Interleukin-1 $\beta$ Inclusion Bodies by Attenuated Total Reflectance FTIR" <i>Biochemistry</i> 33:2628-2634. ✓
W.A.B.		Paladini and Weber (1981) "Pressure-Induced Reversible Dissociation of Enolase" <i>Biochemistry</i> 20:2587-2593. ✓
W.A.B.		Panick et al. (1998) "Structural Characterization of the Pressure-Denatured State and Unfolding/Refolding Kinetics of Staphylococcal Nuclease by Synchrotron Small-Angle X-Ray Scattering and Fourier-Transform Infrared Spectroscopy" <i>J. Mol. Biol.</i> 275:389-402. ✓
W.A.B.		Przybycien et al. (1994) "Secondary Structure Characterization of $\beta$ -Lactamase Inclusion Bodies" <i>Protein Engineering</i> 7:131-136. ✓



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<i>Ratner</i>			Ratner et al. (1990) "Persistent Cutaneous Insulin Allergy Resulting from High-Molecular-Weight Insulin Aggregates" <i>Diabetes</i> 39:728-733.
<i>Ruan</i>			Ruan and Weber (1988) "Dissociation of Yeast Hexokinase by Hydrostatic Pressure" <i>Biochemistry</i> 27:3295-3301.
<i>Rudolph</i>			Rudolph, R. (1990) "Renaturation of Recombinant, Disulfide-Bonded Proteins from 'Inclusion Bodies'" In: <i>Modern Methods in Protein and Nucleic Acid Research</i> (Tschesche, H. ed.) pp. 149-171.
<i>Rudolph</i>			Rudolph and Lilie (1996) "In vitro Folding of Inclusion Body Proteins" <i>The FASEB Journal</i> 10:49-56.
<i>Smeller</i>			Smeller et al. (1999) "Pressure Effect on the Temperature-Induced Unfolding and Tendency to Aggregate of Myoglobin" <i>Biochemistry</i> 38:3816-3820.
<i>Tang</i>			Tang and Ruan (1996) "Pressure-Induced Dissociation of Beef Liver L-Glutamate Dehydrogenase" <i>Progress in Biotechnology</i> 13:163-166.
<i>Thornton</i>			Thornton and Ballow (1993) "Safety of Intravenous Immunoglobulin" <i>Archives of Neurology</i> 50:135-136.
<i>Valax</i>			Valax and Georgiou (1993) "Molecular Characterization of $\beta$ -Lactamase Inclusion Bodies Produced in <i>Escherichia coli</i> . 1. Composition" <i>Biotechnology Progress</i> 9:539-547.
<i>Vandenbroeck</i>			Vandenbroeck et al. (1993) "Refolding and Single-Step Purification of Porcine Interferon- $\gamma$ from <i>Escherichia coli</i> Inclusion Bodies" <i>European Journal of Biochemistry</i> 215:481-486.
<i>Weber</i>			Weber, G. (1987) "Dissociation of Oligomeric Proteins by Hydrostatic Pressure" In: <i>High Pressure Chemistry and Biochemistry</i> (R. van Eldik and J. Jonas, eds.) pp. 401-420.
<i>Yamaguchi</i>			Yamaguchi et al. (1996) "High Pressure NMR Study of Protein Unfolding" <i>Progress in Biotechnology</i> 13:141-146.
<i>Zong</i>			Zong et al. (1995) "High-Pressure-Assisted Reconstitution of Recombinant Chloroperoxidase" <i>Biochemistry</i> 34:12420-12425.

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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<i>Randy</i>			Dewa et al. (1998) "Compression Refolding of Cytochrome C" Protein and Peptide Letters 5:265-268. ✓
<i>ALB</i>			Gorovits et al. (1995) "High Hydrostatic Pressure Induces the Dissociation of cpn60 Tetradecamers and Reveals a Plasticity of the Monomers" The Journal of Biological Chemistry 5:2061-2066. ✓

EXAMINER

*Randy*

DATE CONSIDERED

3-Nov-00

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.